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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/878,131	06/08/2001	Guofan Hong	Lee113	1143

7590

02/05/2003

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 02/05/2003

181

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/878,131

Applicant(s)

HONG ET AL.

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 18-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 18-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' response to the office action (Paper No. 15) filed on October 29, 2002 has been entered and considered.
2. The Drawings (Paper No. 16) filed on October 29, 2002 have been entered.
3. The IDS (Paper No. 17) filed on October 29, 2002 has been entered and considered.

Response to Arguments

4. Applicants' response and arguments (Paper No. 15) have been fully considered and found persuasive.
4. The objection made in the previous office action for drawings is withdrawn herein in view of the applicants' amendment (Paper No.15).
5. Applicants' arguments and amendment (Paper No. 15) with respect to the rejection under 35 U.S.C. 112, second paragraph, has been considered and found persuasive in part. the rejection is withdrawn in view of applicants' arguments and amendment.
6. Applicant's arguments (Paper No.12) with respect to the rejection made in the previous office action under 35 U.S.C. 102(b) to 1-8 has been considered and found not persuasive. Applicants argue that Fuller mentions glycerol level of 10-50% (v/v) and glycol level of 20% with no data showing how it works and does not teach generation of sequence-specific amplification products. This argument is irrelevant to the instant context since the limitation "sequence-specific amplification products" is not in the instant claims. Fuller mentions the range of glycerol concentrations and the temperature range which meet the limitations as amended in the instant claim 1 (that is about 10-20% glycerol and annealing temperatures between about 45⁰ C – about 65⁰ C, melting temperatures of about 70⁰ C). The reference cited by the Applicants' is fully

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considered, however, the reference does not commensurate with the instant claims since the limitation "sequence-specific PCR products" is not found in the instant claims. Further the Bca DNA polymerase disclosed by Fuller inherently possesses proof-reading activity and hence performs similar function as claimed in the instant claim. Thus the rejection is maintained herein.

7. Applicants' arguments and amendment with respect to the rejection made in the previous office action under 35 U.S.C. 103(a) to claims 9-11 have been considered and found not persuasive. Applicants' arguments with reference to the primary reference (Fuller) are found not persuasive as discussed above. Further Applicants' argument that the combination of the teachings of Fuller and Ruano does not make the invention obvious is fully considered and found not persuasive because as discussed above the limitation upon which Applicants' argument was based, that limitation (sequence-specific amplification products) is not in the claims. Therefore the combination of the teachings does make the instant claims obvious and hence the rejection is maintained herein.

New issues

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined

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was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

A. Claims 1-11 and 18-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Hong et al. (USPN. 5,834,253).

With reference to the instant claims 1-3, 9-10, Hong et al. teach a method for extending an oligonucleotide primer using an enzymatic cycle primer extension reaction at annealing temperatures between 45 C and about 60 C and melting temperature of about 70 C (see column 12, lines 46-55) comprising (i) mixing a template with a primer and extending the primer using a DNA polymerase which has proof-reading 3'-5' exonuclease activity, such that the DNA polymerase functions to excise mismatched nucleotides from 3'-terminus of the DNA strand at a faster rate than the rate at which the DNA polymerase functions to remove nucleotides matched correctly with nucleotides of the template under conditions that DNA polymerase repeatedly extends the primer (see column 12, lines 1-13, column 36, lines 16-41); Hong et al. also teach that the method comprises (i) about 10% (w/v) glycerol, (see column 19, lines 6-11); (ii) DNA polymerase selected from *Bacillus stearothermophilus* (see column 12, lines 14-24); method also comprises nucleotide analogs, such as ddNTPs, dITP which reduce innate selective discrimination against the incorporation of fluorescent dye-labelled ddNTPs (see column 12, lines 56-64).

With reference to the instant claims 4, 11, 18-21, Hong et al. teach that the method comprises DNA polymerase having homology (99-100%) to the instant claimed SEQ ID Nos. 1-4 (see sequence alignment).

With reference to the instant claims 5-8, Hong et al. teach that the method comprises repeated cycle primer extension (see column 11, lines 59-65, column 18, lines 60-62); double-stranded DNA sequencing (see column 20, lines 13-21); comprises different length primers (see column 16, lines 60-67, column 17, lines 1-3) and extension of a primer of different length in the presence of ddNTS (see column 18, lines 55-67, column 19, lines 1-45). Thus the disclosure of Hong et al. meets the limitations in the instant claims.

B. Claims 22-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Hong et al. (USPN. 6,165,765).

With reference to the instant claims 22-23, 28-31, Hong et al. teach a method for extending an oligonucleotide primer using an enzymatic cycle primer extension reaction at annealing temperatures between 45 C and about 60 C and melting temperature of about 70 C (see column 8, lines 5-7) comprising (i) mixing a template with a primer and extending the primer using a modified or unmodified DNA polymerase which has an ability to reduce selective discrimination against incorporation of fluorescent dye-labeled ddNTPs, ddCTP and ddATP, in the presence of the dNTS or their analogs and fluorescent ddNTPS (see column 10, lines 42-57, column 15, lines 50-67, column 16, lines 1-16). Hong et al. also teach that the method comprises (i) about 10% (w/v) glycerol, (see column 23, lines 3-31); (ii) DNA polymerase selected from *Bacillus stearothermophilus*, *Bacillus caldotenax*, or *Bacillus caldolyticus* (see column 6, lines 48-64); method also comprises nucleotide analogs, such as ddCTP, ddATP which reduce innate selective discrimination against the incorporation of fluorescent dye-labeled ddNTPs (see column 6, lines 48-64).

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With reference to the instant claims 24-27, 32-35, Hong et al. teach that the method comprises DNA polymerase having homology (99-100%) to the instant claimed SEQ ID Nos. 1-4 (see sequence alignment).

With reference to the instant claim 29, extension of a primer of different length in the presence of ddNTS (see column 17, lines 1-23). Thus the disclosure of Hong et al. meets the limitations in the instant claims.

C. Claims 22-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Hong et al. (USPN. 6,485,909).

With reference to the instant claims 22-23, 28-31, Hong et al. teach a method for extending an oligonucleotide primer using an enzymatic cycle primer extension reaction at annealing temperatures between 45 C and about 60 C and melting temperature of about 70 C (see column 8, lines 8-10) comprising (i) mixing a template with a primer and extending the primer using a modified DNA polymerase which has an ability to reduce selective discrimination against incorporation of fluorescent dye-labeled ddNTPs, ddCTP and ddATP, in the presence of the dNTS or their analogs and fluorescent ddNTPS (see column 41, lines 1-24). Hong et al. also teach that the method comprises (i) about 10% (w/v) glycerol, PEG (see column 23, lines 9-35); (ii) DNA polymerase selected from *Bacillus stearothermophilus*, *Bacillus caldotenax*, or *Bacillus caldolyticus* (see column 7, lines 11-28); method also comprises nucleotide analogs, such as ddCTP, ddATP which reduce innate selective discrimination against the incorporation of fluorescent dye-labeled ddNTPs (see column 6, lines 51-67).

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With reference to the instant claims 24-27, 32-35, Hong et al. teach that the method comprises DNA polymerase having complete homology (100%) to the instant claimed SEQ ID Nos. 1-4 (see sequence alignment).

With reference to the instant claim 29, extension of a primer of different length in the presence of ddNTS (see column 17, lines 1-23). Thus the disclosure of Hong et al. meets the limitations in the instant claims.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,485,909. Although the conflicting claims are not identical, they are not patentably distinct from each other because as detailed above in the rejection under 35 USC 102(e), the patented claims encompass the instant claim limitations. The difference between patented and instant claims is an obvious variation in the reaction conditions. Hence the instant claims are rejected herein under obviousness double patenting.

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
Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-305-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Suryaprabha Chunduru
January 31, 2003


JEFFREY FREDMAN
PRIMARY EXAMINER